Last Month at the Federal Circuit

April 2015

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Abbreviations

AIA	America Invents Act
ALJ	Administrative Law Judge
ANDA	Abbreviated New Drug Application
APA	Administrative Procedures Act
APJ	Administrative Patent Judge
Board	Patent Trial and Appeal Board (formerly the Board of Patent Appeals and Interferences)
Commissioner	Commissioner of Patents and Trademarks
CIP	Continuation-in-Part
DJ	Declaratory Judgment
DOE	Doctrine of Equivalents
FDA	Food and Drug Administration
IDS	Information Disclosure Statement
ITC	International Trade Commission
JMOL	Judgment as a Matter of Law
MPEP	Manual of Patent Examining Procedure
NDA	New Drug Application
PCT	Patent Cooperation Treaty
PTO	United States Patent and Trademark Office
SJ	Summary Judgment
TTAB	Trademark Trial and Appeal Board

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Lost Profits Must Come from the Lost Sales of a Product or Service the Patentee Itself Sells

Hongbiao (Bill) Yu

Judges: Lourie, Dyk (author), Reyna

[Appealed from S.D. Cal., Judge Bencivengo]

In *Warsaw Orthopedic, Inc. v. NuVasive, Inc.*, Nos. 13-1576, -1577 (Fed. Cir. Mar. 2, 2015), the Federal Circuit affirmed the district court's finding of invalidity and infringement of the patents-at-issue, vacated the district court's damages award, and remanded for a new trial on damages.

Warsaw Orthopedic, Inc. ("Warsaw") owns U.S. Patent Nos. 5,860,973 ("the '973 patent") and 6,945,933 ("the '933 patent"), and NuVasive, Inc. ("NuVasive") owns U.S. Patent No. 7,470,236 ("the '236 patent"). Warsaw sued NuVasive for infringement of its '973 and '933 patents, and NuVasive counterclaimed for infringement of its '236 patent. At trial, the jury found (1) the asserted claims of the '973 patent were valid, (2) the asserted claims of the '933 patent were infringed under the DOE, and (3) the asserted claims of the '236 patent were infringed. The jury awarded damages for each. After trial, Warsaw filed motions seeking supplemental damages and a permanent injunction with respect to its '973 and '933 patents, and a motion for JMOL or a new trial with respect to the jury's finding of infringement of the '236 patent. NuVasive also moved for JMOL or a new trial with respect to the jury's finding of validity of the '973 patent, infringement of the '933 patent, and Warsaw's entitlement to lost profits. The district court denied the motions for JMOL or a new trial, denied Warsaw's requests for supplemental damages and a permanent injunction, and set ongoing royalty rates. Both parties appealed.

On appeal, the Federal Circuit addressed these issues in turn. On the issue of invalidity of the '973 patent, the Court held that the district court did not err in either the claim construction or the jury instructions. Specifically, with respect to claim 35 of the '973 patent, the Court found no error in the district court's conclusion that the preamble is not limiting. In addition, the Court found no error in the district court's instruction to the jury that "said implant" refers to "a spinal implant capable of being inserted translaterally," and that "capable" should be given its plain meaning. Slip op. at 6 (citation omitted). Finally, the Court held that because Warsaw presented substantial evidence to the jury distinguishing the '973 patent from the prior art references relied upon by NuVasive, the jury was entitled to find that the prior art references did not anticipate or render obvious the asserted claims of the '973 patent.

"To be entitled to lost profits, we have long recognized that the lost profits must come from the lost sales of a product or service the patentee itself was selling." Slip op. at 19.

In response to NuVasive's argument that the asserted claims of the '973 patent were indefinite because of the relative nature of the claim limitation, the Federal Circuit held that the relative nature of the claim does not itself make it indefinite under the standard for determining indefiniteness set forth by the Supreme Court in *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120 (2014). Noting that both parties stipulated that the average dimensions of human vertebrae are well known, the Court held that NuVasive failed to show that human anatomy varies so significantly that reliance on the well-known dimensions of human vertebrae makes the claims indefinite.

On the issue of infringement of Warsaw's '933 patent, the Federal Circuit held that substantial evidence exists to support the jury's finding of infringement under the DOE. NuVasive argued that its accused product did not literally infringe the claimed two-prong device because the accused product includes three prongs instead of two prongs, and that the third prong of the accused product was not capable of lateral movement or pivoting, whereas both prongs of the claimed device were capable of lateral movement. Noting that NuVasive's own witnesses admitted that two and three prongs are equivalent, the Court held that Warsaw had submitted substantial evidence to show that the difference between the accused device and the patented technology was insubstantial.

On the infringement issue of the '236 patent owned by NuVasive, the Federal Circuit held that substantial evidence exists to support the jury's finding of infringement. The focus of the issue was whether the accused product of Medtronic Sofamor Danek USA, Inc. ("MSD"), a company related to Warsaw, "stop[s] the emission of said stimulus signal immediately after said predetermined neuromuscular response is detected," as required by claim 1 of the '236 patent. Slip op. at 11 (citation omitted). Based on the claim construction presented to the jury, the Court agreed with NuVasive's claim construction that a "restart" is a type of stop. *Id*. at 12. In addition, noting that MSD was aware of the '236 patent prior to litigation and specifically instructed doctors to use the product during surgical procedures in an infringing manner, the Court held that NuVasive had put forth enough evidence to support a jury's finding of induced infringement. Finally, the Court rejected MSD's argument that interpreting the "stopping" step in such a way was barred by the prosecution history because MSD or Warsaw failed to present to the jury any construction of the "stopping" step beyond its plain and ordinary meaning. The Court explained that "where the parties and the district court elect to provide the jury only with the claim language itself, and do not provide an interpretation of the language in the light of the specification and the prosecution history, it is too late at the JMOL stage to argue for or adopt a new and more detailed interpretation of the claim language and test the jury verdict by that new and more detailed interpretation." *Id.* at 13 (quoting *Hewlett-Packard Co. v. Mustek Sys., Inc.*, 340 F.3d 1314, 1321 (Fed. Cir. 2003)).

The Federal Circuit then addressed the damages issues relating to the '973 and '933 patents. The Court first noted that under 35 U.S.C. § 284 and *SmithKline Diagnostics, Inc. v. Helena Laboratories Corp.*, 926 F.2d 1161, 1164 (Fed. Cir. 1991), "a patentee is entitled to either a reasonable royalty or lost profits—not both." Slip op. at 15. The Court further noted that a patentee may not claim, as its own damages, the lost profits of a related company. Under these principles, the Court rejected Warsaw's claim of lost profits from sales of fixations to MSD. The Court characterized this claim as based on the theory of convoyed sales, which is a sale of a product that is not patented, but is sufficiently related to the patented product such that the patentee may recover lost profits for lost sales. The Court explained that to be entitled to lost profits for convoyed sales, the related products must be functionally related to the patented product and losses must be reasonably foreseeable. "Being sold together merely for 'convenience or business advantage' is not enough." *Id.* at 17 (quoting *Am. Seating Co. v. USSC Grp., Inc.*, 514 F.3d 1262, 1268 (Fed. Cir. 2008)). The Court held that Warsaw failed to prove a functional relationship necessary to support an award of lost profits for convoyed sales because including the fixations within a kit is the precise sort of convenience or business strategy excluded by the case law.

The Federal Circuit also held that Warsaw cannot recover as lost profits the lost royalty payments from two companies related to Warsaw. The Court rejected Warsaw's argument that it is not seeking damages that these related companies suffered, but rather the money that it would otherwise have received but for NuVasive's infringement. The Court explained that it is a long recognized principle that the lost profits must come from the lost sales of a product or service the patentee itself was selling. Noting that Warsaw did not sell any product, the Court held that Warsaw failed to prove that its profits

from selling a product have been lost due to NuVasive's infringing sales.

The Federal Circuit further held that Warsaw cannot recover the "true-up" payments made by MSD to Warsaw because they were not lost profits. The Court reasoned that Warsaw made no effort to distinguish what percentage of the true-ups was attributable to the royalty payments as opposed to payments on unrelated transactions. The Court also noted that the transfer pricing policies between MSD and Warsaw indicated that "the true-ups are established on a company-by-company, not a technology-by-technology or even a product-by-product, basis." *Id.* at 20.

On the issue of reasonable royalty for Warsaw's '973 and '933 patents, the Federal Circuit remanded for a new trial to determine a reasonable royalty because it was not entirely clear in the jury's verdict which period the reasonable royalty was determined for or whether the jury impermissibly relied on evidence not probative of the value of the patented technology. In view of the remand for a new trial, the Federal Circuit then declined to resolve the issue of whether the district court erred in not awarding supplemental damages to Warsaw. Finally, because the ongoing royalty set by the district court impermissibly included a lost profits component, the Federal Circuit vacated the district court's award and remanded for the district court to determine an appropriate ongoing royalty rate.

Accordingly, the Federal Circuit affirmed the district court with respect to invalidity and infringement, vacated Warsaw's damages award, and remanded for a new trial on damages.

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Federal Circuit Rejects District Court's Construction of "At Least One Of" as "One or More"

Kelly S. Horn

Judges: Prost (author), Newman (dissenting), Linn

[Appealed from D. Conn., Judge Arterton]

In *Enzo Biochem Inc. v. Applera Corp.*, No. 14-1321 (Fed. Cir. Mar. 16, 2015), the Federal Circuit reversed the district court's claim construction, vacated the jury's finding of infringement, and remanded for further proceedings under the Court's articulated claim construction.

Enzo Biochem Inc., Enzo Life Sciences, Inc., and Yale University (collectively "Enzo") asserted claims of U.S. Patent No. 5,449,767 ("the '767 patent") against Applera Corp. and Tropix, Inc. (collectively "Applera"). The claims are generally directed to nucleotide probes used in nucleic acid labeling and detection. The detectable signal may be generated either from a label itself ("direct detection") or from a secondary chemical agent that is bound to the label ("indirect detection"). The district court construed the phrase "A comprises at least three carbon atoms and represents *at least one* component of a signalling moiety capable of producing a detectable signal" as "A comprises at least three carbon atoms and is *one or more* parts of a signalling moiety, which includes, in some instances, the whole signalling moiety." Slip op. at 7 (emphases added) (quoting *Enzo Biochem, Inc. v. Applera Corp.*, No. 3:04-CV-929, 2006 WL 2927500, at *2, *4 (D. Conn. Oct. 12, 2006)). The district court further construed the claim term "signalling moiety" as "a chemical entity capable of producing a detectable signal." *Id.* (quoting *Enzo Biochem*, 2006 WL 2927500, at *2, *4). The district court's construction allowed for both direct and indirect detection of the claimed compound. Based on this construction, a jury found that the asserted claims were infringed and that the '767 patent was not invalid for lack of written description and enablement. Applera appealed.

"[T]he phrase 'at least one component of a signalling moiety' indicates that the signalling moiety is composed of multiple parts as the term 'component' in and of itself indicates a multipart system." Slip op. at 9.

On appeal, the Federal Circuit rejected the district court's claim construction, holding that the claims should have been construed to cover only indirect detection. The Court found that the language of the claims supported such a construction. Specifically, the Court held that the phrase "at least one component of a signalling moiety" suggests that the moiety is composed of multiple parts because the "term 'component' in and of itself indicates a multipart system." *Id.* at 9. The Court concluded that it would therefore be improper to construe the phrase to allow for a single-component system because such a construction "would read out the phrase 'component of a signalling moiety.'" *Id.* at 9-10. Further, the Court reasoned that since the claim language requires that "A" be attached through a linkage group

that "does not substantially interfere with formation of the signalling moiety," then "'A' cannot be the whole signalling moiety, as the claimed compound does not include a *formed* signalling moiety." *Id.* at 10 (citation omitted).

The Federal Circuit rejected the argument that the term "at least one of" allows for both direct and indirect detection under *Howmedica Osteonics Corp. v. Wright Medical Technology, Inc.*, 540 F.3d 1337 (Fed. Cir. 2008), in which "at least one" was construed to mean "one or more." Slip op. at 10-11 (quoting *Howmedica*, 540 F.3d at 1344). Specifically, the Court held that *Howmedica* was inapposite because, "unlike in *Howmedica* where the claim did not require the prosthetic knee to have more than one condylar element, here the plain reading of the disputed claim term requires that a signalling moiety be composed of components, of which at least one is 'A.'" *Id.* at 11.

The Federal Circuit also found support for its claim construction in the specification. First, the Court found that the specification "never [describes] that 'A' alone can be a signalling moiety." *Id*. Second, the Court relied on the specification's background section, which "describes how 'A,' a biotin, iminobiotin, or lipoic acid, forms a detectable unit, i.e., a signalling moiety, upon interaction with avidin or antibodies." *Id.* at 11-12. Third, the Court stated that the only discussion of direct detection was in the context of explaining that indirect detection is superior. The Court also noted that the portions of the specification pointed to by Enzo during oral argument, considered alone or in combination with Enzo's expert's testimony, also did not support a disclosure of direct detection.

Based on the language of the claims and the specification, the Court concluded that the district court erred in construing the asserted claims to cover both direct and indirect detection. Accordingly, the Court reversed the district court's claim construction, vacated the jury's finding of infringement, and remanded the case for further proceedings consistent with the Court's claim construction.

Judge Newman dissented. In her opinion, Judge Newman reasoned that "[t]he rules of grammar and linguistics, even in legal documents, do not establish that 'at least one' means two or more." Newman Dissent at 4. Further, Judge Newman noted that the district court construed "at least one" not just based on grammar and linguistics, but also based on the intrinsic record and extrinsic evidence. Judge Newman believed that in view of the recent Supreme Court decision in *Teva Pharmaceuticals USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831 (2015), "appropriate deference must be given to the findings of the district court." Slip op. at 5. Since there was no illustrated error of fact or law in her opinion, Judge Newman opined that there were no grounds for reversing the district court's claim construction.

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Means-Plus-Function Terms Are Defined by What the Specification and Prosecution History Say, Rather Than What They Do Not Say

Ming W. Choy

Judges: Taranto, Bryson, Chen (author)

[Appealed from D. Del., Judge Robinson]

In *MobileMedia Ideas LLC v. Apple Inc.*, Nos. 14-1060, -1091 (Fed. Cir. Mar. 17, 2015), the Federal Circuit affirmed-in-part, reversed-in-part, and vacated-in-part the district court's finding of infringement, invalidity, and claim construction with respect to the patents-in-suit and remanded to the district court for further proceedings.

MobileMedia Ideas LLC ("MobileMedia") owns U.S. Patent Nos. 6,427,078 ("the '078 patent") related to camera phones; 6,070,068 ("the '068 patent") related to call handling; 6,253,075 ("the '075 patent") related to call rejection; and RE 39,231 ("the '231 patent") related to call alerts (collectively "the patents-in-suit"). MobileMedia sued Apple Inc. ("Apple") for infringement of the patents-in-suit and other patents not at issue on appeal. Prior to trial, the district court granted SJ of noninfringement of claims 2-4 and 12 of the '231 patent. After trial, a jury returned a verdict finding that Apple's accused products directly infringed the asserted claims of the '075 patent, the '068 patent, and the '078 patent; that Apple did not induce infringement of the asserted claims; and that none of the asserted claims were invalid as obvious.

After the district court entered a judgment consistent with the jury's verdict, Apple renewed a previously filed motion for JMOL and, in the alternative, moved for a new trial. The district court granted Apple's JMOL motion of noninfringement and invalidity of the asserted claims of the '075 patent and invalidity of claim 24 of the '068 patent, but denied Apple's JMOL motion of invalidity of claim 23 and noninfringement of claims 23 and 24 of the '068 patent, and invalidity and noninfringement of claim 73 of the '078 patent.

Apple appealed the district court's claim construction related to the '078 and '068 patents, the district court's determination that substantial evidence was presented supporting the jury's finding of lack of motivation to combine references to render claim 73 of the '078 patent obvious, and the district court's conclusion that claim 23 of the '068 patent would not have been obvious. MobileMedia cross-appealed the district court's grant of JMOL of noninfringement and invalidity of the asserted claims of the '075 patent and of SJ of noninfringement of the '231 patent.

"The scope of a means-plus-function limitation is outlined not by what the specification and prosecution history *do not* say, but rather by what they *do* say." Slip op. at 16.

On appeal, the Federal Circuit determined that substantial evidence supported the jury's finding that claim 73 of the '078 patent was nonobvious over two prior art references, but agreed with Apple that the jury's finding of infringement was based on the district court's erroneous claim construction. On invalidity, the Court observed that the existence of a motivation to combine the prior art references was contested by the parties at trial. The Court stated that, although Apple presented evidence that a skilled artisan would have been motivated to combine the prior art references, that alone did not demonstrate that the jury's verdict of nonobviousness was unsupported by substantial evidence. The Court observed that MobileMedia's expert provided a reasonable basis for the jury finding that combining the references would have been beyond the technical ability of a skilled artisan at the relevant time frame due to the "complexity and sophistication of software and hardware integration and development." Slip op. at 8 (quoting *MobileMedia Ideas LLC v. Apple Inc.*, 966 F. Supp. 2d 439, 471 (D. Del. 2013)). In particular, the Court noted that MobileMedia's expert provided evidence showing that it took Nokia Corporation two years to develop a product that provided the claimed functionality between a phone and camera. Although Apple's expert provided a differing opinion, the Court held that the jury was permitted to make credibility determinations and believe the witness it considered more trustworthy. Accordingly, the Court held that substantial evidence supported the jury's finding that claim 73 was nonobvious over the cited prior art.

The Court then considered the district court's constructions of means-plus-function terms in claim 73 of the '078 patent, finding the construction of "means for processing and for storing" erroneous. The Court disagreed with the district court that the "means for processing and for storing" could cover any image processing unit in a device. After examining the plain language of claim 73 and the '078 patent's specification, the Court concluded that the function is performed by a processor and memory unit of a camera unit of a device, and not by the device's general purpose central processor. Because Apple's accused products did not have a processor or internal memory for storing image data in the camera unit, the Court concluded that the accused products did not infringe and reversed the district court's finding of infringement.

Turning next to the '068 patent, the Court also found that substantial evidence did not support the jury's finding that claim 23 was not obvious based on U.S. Patent No. 5,754,636 ("Bayless"). The Court noted that, during trial, Apple's expert explained why a skilled artisan would have found it obvious to modify Bayless's teaching of displaying a call handling options window after a user presses two keys in a serial sequence to use a single predetermined selection operation, as recited in claim 23, using common knowledge possessed by those of skill in the art. The Court then observed that MobileMedia's expert provided only conclusory opinions to rebut Apple's obviousness assertion. Accordingly, the Court held that "there [was] no substantial evidence to support a conclusion that a skilled artisan would not have found it obvious" to modify Bayless in the manner claimed in claim 23. *Id.* at 21. Because the Court did find the claim obvious, it did not reach Apple's argument that the accused products did not infringe claim 23 of the '068 patent.

The Court then turned to MobileMedia's cross-appeals. The Court first considered and affirmed the district court's grant of JMOL of invalidity of the asserted claims of the '075 patent, finding that the claims of the '075 patent were obvious over Global System for Mobile communications ("GSM") protocols GSM 04.08 and GSM 04.83. The Court noted that there was no dispute that GSM 04.08 and GSM 04.83 disclosed every limitation of the asserted claims, but the parties disputed whether one of ordinary skill in the art would have been motivated to combine the two GSM standards at the time of the alleged invention. The Court found that Apple's expert provided several reasons why a skilled artisan would have combined the two protocols, including that the two protocols were part of the same standard, that GSM 04.83 expressly referenced GSM 04.08 "in numerous places," and that the referenced sections of the publications of the two protocols were labeled in a "similar" manner. *Id.* at 28. The Court noted that MobileMedia's expert had provided only conclusory opinions about why GSM 04.08 alone did not render the asserted claims obvious. Accordingly, the Court agreed with the district court that "no substantial evidence supports a determination that one of ordinary skill in the art would not have been motivated to combine . . . GSM 04.83 and . . . GSM 04.08," and affirmed the district court's grant of JMOL of invalidity. *Id.* at 32. The Court then declined to decide MobileMedia's appeal from the district court's grant of JMOL of noninfringement.

Turning next to the '231 patent, the Court agreed with MobileMedia that the district court's grant of SJ of noninfringement was based on an erroneous construction of the claim. The Court considered the construction of the "control means" and "to change a volume of the generated alert sound," which are means-plus-function terms under 35 U.S.C. § 112, sixth paragraph. The Court also noted that the only structure recited in the specification to perform the claimed function is a phone's CPU and an alert sound generator on/off controller, which "controls the alert sound generator to change a volume of the generated alert sound by either stopping the alert sound or reducing a volume of the alert sound." *Id*. at 35. The Court disagreed with the district court's conclusion that reducing the sound and stopping the sound were mutually exclusive, and concluded that the claimed "chang[ing] a volume" encompasses both "stop[ping] the sound" and "reduc[ing] the volume of the sound." *Id.* (alterations in original) (citation omitted). Based on this analysis, the Court vacated the district court's grant of SJ of noninfringement because it was based on the erroneous construction and remanded to the district court for further proceedings.

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Failure to Read Mislabeled Court Orders Alone Does Not Constitute Good Cause or Excusable Neglect Required for Extending Appeal Period

Hongbiao (Bill) Yu

Judges: Dyk (dissenting), O'Malley (author), Wallach

[Appealed from W.D. Tex., Judge Garcia]

In *Two-Way Media LLC v. AT&T, Inc.*, No. 14-1302 (Fed. Cir. Mar. 19, 2015), the Federal Circuit affirmed the district court's denial of a motion to extend or reopen the appeal period under Fed. R. App. P. 4(a)(5) and (6) because the movant failed to show good cause or excusable neglect required by Rule 4(a)(5) and did not meet the lack of notice requirement of Rule 4(a)(6).

Two-Way Media LLC ("TWM") filed suit against AT&T, Inc.; AT&T Corp.; AT&T Operations, Inc.; AT&T Services, Inc.; SBC Internet Services, Inc.; and Southwestern Bell Telephone Co. (collectively "AT&T"), alleging infringement of two patents. After a jury trial, the district court entered final judgment, and AT&T timely filed four motions for renewed JMOL or a new trial, three of which were confidential and filed under seal. The district court denied all of AT&T's motions and granted TWM's request for costs. When the court initially docketed the denials, it labeled the three orders addressing the confidential motions as orders granting the motions to seal, without indicating that the same orders denied the relief sought in the underlying motions. The parties received notice of electronic filings ("NEFs") for each of those orders. The underlying orders, which could be accessed by clicking on the hyperlink in the NEFs, denied the merits of AT&T's JMOL motions. The district court also docketed its order denying AT&T's fourth, nonconfidential JMOL and its order on TWM's Bill of Costs. Three days later, the district court updated the description of the orders on the docket to reflect that AT&T's motions for JMOL had been denied, but did not send new NEFs to the parties. After the appeal period expired, AT&T filed a motion to extend or reopen the appeal period under Rules 4(a)(5) and (6). The district court denied AT&T's motion. AT&T appealed.

On appeal, the Federal Circuit held that the district court did not abuse its discretion in denying AT&T's motion to extend or reopen the appeal period under Rules 4(a)(5) or (6). Rule 4(a)(5) provides that, to qualify for an extension of the appeal period, the moving party must show excusable neglect or good cause. Rule 4(a)(6) provides that a court may reopen the appeal period if the court finds that the moving party did not receive notice of the entry of the judgment or order. The Court held that AT&T failed to show good cause or excusable neglect required by Rule 4(a)(5), and that Rule 4(a)(6) is inapplicable because AT&T received the notice.

"[E]ven a complete lack of notice would not qualify as excusable neglect under Rule 4(a)(5), without some additional showing." Slip op. at 6.

The Federal Circuit first addressed the issue of whether AT&T's failure to read the underlying district court order constituted good cause or excusable neglect under Rule 4(a)(5). The Court rejected AT&T's argument that its delay should be excused because it received incomplete NEFs and the district court did not reissue new NEFs when it corrected the docket entries. The Court agreed with the district court that even a complete lack of notice would not qualify as excusable neglect under Rule 4(a)(5), without some additional showing. Otherwise, as explained by the Court, allowing Rule 4(a)(5) to be triggered so easily would render Fed. R. Civ. P. 77(d)(2) a nullity. Fed. R. Civ. P. 77(d)(2) provides that "[l]ack of notice of the entry does not affect the time for appeal or relieve—or authorize the court to relieve—a party for failing to appeal within the time allowed, except as allowed by Federal Rule of Appellate Procedure 4(a)."

The Federal Circuit also rejected AT&T's argument that this is not just a "lack of notice" case, but a case involving an "affirmatively misleading notice" that violated Fed. R. Civ. P. 79. Slip op. at 7. The Court held that AT&T was wrong in arguing that the notice violated Rule 79 because it applies to the civil docket, not to electronic email notices. The Court noted that, although the district court did not send updated NEFs, the district court promptly corrected the docket entries to state that the orders denied the underlying JMOL motions.

The Federal Circuit disagreed with AT&T's argument that its failure to read the district court's order was excusable, because it was misled into doing so by the district court itself. The Court recognized that excusable neglect is not limited strictly to omission caused by circumstances beyond the control of the movant, and that a court's own conduct, such as misleading entries or statements to counsel, is relevant to determine whether neglect not predicated only on a failure to receive notice of an entry of judgment can, or should, be deemed excusable. The Court noted that the trial court examined all relevant circumstances surrounding the admitted neglect by AT&T's counsel, including the fact that AT&T received an order denying its unsealed JMOL motion and an order assigning costs at the same time it received the allegedly misleading NEFs. The Court explained that an order assessing costs was a clear indication to AT&T that TWM was the prevailing party. The Court also noted that the orders and NEFs had been sent to eighteen different counsel and legal assistants representing AT&T, and that at least some of those recipients downloaded the full text of the orders. Given these circumstances, the Court held that the district court did not abuse its discretion in concluding that it was inexcusable for AT&T's counsel to fail to read all of the underlying orders they received.

The Federal Circuit then addressed the issue of whether AT&T satisfied the requirement for reopening the appeal period under Rule 4(a)(6). Agreeing with the district court's finding that AT&T received the notice of the entry of judgment when it received and downloaded those judgments, the Court held that the trial court did not err in finding that AT&T failed to establish that it did not receive the notice contemplated in Rule 4(a)(6)(A). The Court also held that the trial court did not abuse its discretion in denying AT&T's motion solely because it did not receive an NEF of the corrected docket entry.

Like the district court, the Federal Circuit declined to hold that the actual receipt of the text of a judgment or order does not constitute notice of the entry of that judgment within the meaning of Rule 4(a)(6)(A), noting that Rule 4(a)(6) does not apply when a party simply shows it did not read a court order. Thus, the Court held that AT&T's argument that it never read the orders because it was confused by the NEFs was irrelevant to Rule 4(a)(6).

The Federal Circuit also rejected AT&T's argument that it never received the type of notice contemplated by Rule 4(a)(6)(A) because it never received an NEF describing the type of docket entry required by Rule 79. The Court noted that, although the NEF was inaccurate, AT&T was notified both that the orders had been entered on the docket and that the order contained final judgments.

Judge Dyk dissented from the majority's holding that the district court did not have discretion to reopen the appeal period under Fed. R. App. P. 4(a)(6). Judge Dyk would have held that Rule 4(a)(6) applied because the substantive orders were not entered on the docket at the time AT&T arguably received notice of the orders, and the required notice of the entry was not provided. Judge Dyk reasoned that the three docket entries concerning the sealing orders did not constitute the required entry with respect to the substantive motion orders because they merely stated that the sealing orders had been granted and did

not mention that the substantive orders were denied. Judge Dyk further reasoned that, because the NEFs were never sent concerning the substantive order docket entries, AT&T never received notice of the entry of the order required by Fed. R. Civ. P. 77(d).

In response to Judge Dyk's dissent, the majority first distinguished the present suit over the cases cited by Judge Dyk, explaining that the facts-at-issue in those cases were not relevant to the question-at-issue, and that neither Rule 4(a)(6) nor the meaning of notice thereunder was at issue in those cases. The majority noted that, regardless of which docket entry—the initial one or the corrected one—triggered AT&T's time for appeal, the appeal was untimely by a large margin. Moreover, the Court noted that the NEFs AT&T did receive stated that all the cited orders were entered on the docket and links to all the orders were provided. The Court found no abuse of discretion for the district court to impose an obligation to monitor an electronic docket for entry of an order which a party and its counsel already have in their possession and know that the clerk at least attempted to enter.

Accordingly, the Federal Circuit affirmed the district court's denial of AT&T's request for relief under both Rules 4(a)(5) and (6).

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Claim Vitiation Does Not Foreclose the DOE

Mark F. Mashack

Judges: Reyna, Linn (author), Wallach
[Appealed from D. Del., Judge Stark]

In *Cadence Pharmaceuticals Inc. v. Exela PharmSci Inc.*, No. 14-1184 (Fed. Cir. Mar. 23, 2015), the Federal Circuit affirmed the district court's claim construction, rulings of literal infringement and infringement under the DOE, and nonobviousness determination of the asserted claims.

SCR Pharmatop and Cadence Pharmaceuticals Inc. (collectively "Cadence") are the owner and exclusive licensee, respectively, of U.S. Patent Nos. 6,028,222 ("the '222 patent") and 6,992,218 ("the '218 patent"), which are directed to stable aqueous acetaminophen formulations. Cadence markets an injectable acetaminophen product, which is approved by the FDA and is marketed under the name Ofirmev®. The FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book") lists the '222 and '218 patents as covering Ofirmev®.

Exela PharmSci Inc. ("Exela") filed an ANDA, seeking approval to market a generic version of Ofirmev®. The ANDA included a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV certification"), asserting that the '222 and '218 patents were invalid and not infringed. In response, Cadence sued Exela for infringing certain claims of the '222 and '218 patents. Following a bench trial, the district court found the '222 patent not invalid and literally infringed, and the '218 patent not invalid and infringed under the DOE. Exela appealed both of the district court's infringement decisions and its validity determination as to the '218 patent. It did not appeal the district court's validity determination as to the '222 patent.

"'Vitiation' is not an exception or threshold determination that forecloses resort to the doctrine of equivalents, but is instead a legal conclusion of a lack of equivalence based on the evidence presented and the theory of equivalence asserted." Slip op. at 11.

On appeal, the Federal Circuit affirmed the district court's judgment with respect to both the '222 and '218 patents. First, the Court stated that Exela's appeal regarding the '222 patent turned on claim construction. Specifically, the district court construed the term "buffering agent" in claim 1 to mean "[a]n agent that helps the formulation resist change in pH." Slip op. at 6 (alteration in original) (quoting *Cadence Pharm., Inc. v. Paddock Labs. Inc.*, 886 F. Supp. 2d 445, 456 (D. Del. 2012)). Exela argued that a buffering agent must be present in sufficient concentration to prevent a material change in pH, relying on particular embodiments and the prosecution history. The Court agreed with the district court, however, finding "nothing in the intrinsic record to warrant adding requirements of effective concentration

or resistance to material change." *Id.* at 7. The Court then affirmed the district court's finding that claim 1 of the '222 patent was infringed based on the district court's finding that sodium ascorbate present in Exela's formulation met the buffering agent limitation as construed by the Court.

Second, the Federal Circuit affirmed the district court's findings regarding the '218 patent. Exela argued that the district court erred in holding that Exela's process infringed the asserted claims under the DOE. Specifically, Exela contended that deoxygenating after adding the active ingredient is the "antithesis" of deoxygenating before adding the active ingredient. *Id*. at 10. Because such a substitution would "vitiate" the claimed limitation, Exela argued, there could be no finding of equivalence, relying on *Planet Bingo, LLC v. GameTech International, Inc.*, 472 F.3d 1338, 1345 (Fed. Cir. 2006). Slip op. at 10. The Court disagreed. The Court stated, "'Vitiation' is not an exception or threshold determination that forecloses resort to the doctrine of equivalents, but is instead a legal conclusion of a lack of equivalence based on the evidence presented and the theory of equivalence asserted." *Id*. at 11. The Court then affirmed the district court's finding of infringement under the DOE, concluding that a reasonable trier of fact could conclude, and in fact did conclude, that Exela's process is insubstantially different from the claimed process.

Exela also argued that the district court erred in concluding that the phrase "optionally topped with an inert gas . . . and placed in a closed container" indicates that the "vacuum stoppering step" was optional. *Id*. at 12 (quoting *Cadence*, 886 F. Supp. 2d at 464). Relying on the specification and prosecution history, Exela argued that the step was mandatory. The Court disagreed. As did the district court, the Court held that the plain and ordinary meaning of the term "optionally" indicated that the step was optional. The Court also examined the specification and found nothing to imply that the invention was limited to embodiments requiring the step to be mandatory. Similarly, the Court agreed with the district court that the prosecution history failed to clearly and unmistakably disavow the unambiguous recitation of the step being optional. Concluding that the step was optional and not mandatory, the Court affirmed the district court's finding of infringement.

Finally, the Court affirmed the district court's determination of nonobviousness. Exela argued that the '218 patent was obvious over the '222 patent in view of a prior art reference. The district court found that it would not have been obvious to combine the reference with the '222 patent because the compound disclosed in the reference process degraded by oxidation, whereas acetaminophen degrades primarily by hydrolysis. The district court also found relevant that the claimed process was "technical[ly] difficult[]." *Id*. at 16 (alterations in original) (quoting *Cadence Pharm., Inc. v. Excela Pharma Scis., LLC*, No. 11-733-LPS, 2013 U.S. Dist. LEXIS 166097, at *105 (D. Del. Nov. 14, 2013)). The district court also found that secondary considerations supported a conclusion of nonobviousness. Specifically, the district court found that Ofirmev® fulfilled a long-felt need, was a commercial success, was licensed and praised in the industry, and exhibited unexpected results. Noting that "Exela [bore] a difficult burden . . . since the Examiner initially rejected the claims . . . for essentially the same reasons" and "patents are presumed to be valid," the Court ultimately agreed with the district court's findings and affirmed its nonobviousness determination. *Id*. at 17.

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No Requirement for the Prior Art to Disclose "Actual Performance" to Anticipate

Mark F. Mashack

Judges: Prost, Newman, Linn (author)

[Appealed from Board]

In *Kennametal, Inc. v. Ingersoll Cutting Tool Co.*, No. 14-1350 (Fed. Cir. Mar. 25, 2015), the Federal Circuit affirmed the Board's determinations of anticipation and obviousness of the claims of U.S. Patent No. 7,244,519 ("the '519 patent").

The '519 patent is directed to cutting tools containing a ruthenium binder and coated using physical vapor deposition ("PVD"). The inventors of the '519 patent assigned their interests in the invention to TDY Industries, Inc. ("TDY"). TDY sued Ingersoll Cutting Tool Co. ("Ingersoll") for infringement of the '519 patent. After filing suit, TDY assigned the '519 patent to Kennametal, Inc. ("Kennametal").

Ingersoll successfully petitioned for inter partes reexamination of the '519 patent, asserting that some of the original claims were anticipated by U.S. Patent No. 6,554,548 ("Grab") and all of the claims were obvious under 35 U.S.C. § 103(a). The examiner did not adopt Ingersoll's proposed anticipation rejections, but rejected all the pending claims as being obvious. In response, Kennametal amended the existing claims and filed new claims. Ingersoll again proposed both anticipation and obviousness rejections. The examiner again refused to adopt the anticipation rejections, but rejected all of the claims as being obvious. Kennametal appealed the rejections and Ingersoll cross-appealed the examiner's refusal to adopt its proposed anticipation rejections. The Board found that the examiner erred in not adopting Ingersoll's proposed anticipation rejections of several claims and affirmed the examiner's obviousness rejections. After the Board denied Kennametal's request for rehearing, Kennametal appealed.

"Though it is true that there is no evidence in Grab of 'actual performance' of combining the ruthenium binder and PVD coatings, this is not required." Slip op. at 11 (quoting *Novo Nordisk Pharm., Inc. v. Bio-Tech. Gen. Corp.*, 424 F.3d 1347, 1355 (Fed. Cir. 2005)).

On appeal, the Federal Circuit first considered Kennametal's argument that Grab did not disclose the combination of ruthenium as a binder and a PVD coating. Rejecting Kennametal's argument that a person of skill in the art would not immediately envisage the claimed combination, the Court found that claim 5 of Grab expressly recited a binder consisting of one of five metals, one of which is ruthenium, together with a coating. The Court determined that, although Grab did not focus on PVD coatings, PVD was one of three disclosed types of coatings. The Court then explained that "[b]ecause all the limitations of Kennametal's claim are specifically disclosed in Grab, the question for the purposes of anticipation is

'whether the number of categories and components' disclosed in Grab is so large that the combination of ruthenium and PVD coatings 'would not be immediately apparent to one of ordinary skill in the art.'" Slip op. at 10 (quoting *Wm. Wrigley Jr. Co. v. Cadbury Adams USA LLC*, 683 F.3d 1356, 1361 (Fed. Cir. 2012)). The Court concluded that, "[t]hough it is true that there is no evidence in Grab of 'actual performance' of combining the ruthenium binder and PVD coatings, this is not required." *Id.* at 11 (quoting *Novo Nordisk Pharm., Inc. v. Bio-Tech. Gen. Corp.*, 424 F.3d 1347, 1355 (Fed. Cir. 2005)). The Court explained that, instead, "anticipation only requires that those suggestions be enabled to one of skill in the art." *Id.* (quoting *Novo Nordisk*, 424 F.3d at 1355). The Court therefore held that substantial evidence supported the Board's finding of anticipation of independent claim 1. The Court also affirmed the Board's finding as to the dependent claims because Kennametal did not separately argue any of the dependent claims. Furthermore, because Kennametal argued the patentability of independent claim 89 only in a footnote, the Court also affirmed the Board's finding of anticipation of claim 89.

The Court next turned to the Board's obviousness findings, first considering Ingersoll's argument that Kennametal failed to independently argue the patentability of the dependent claims at the Board and had thereby waived its right to challenge the Board's obviousness determinations for those claims. Rejecting this argument, the Court observed that Kennametal faced a different set of rejections at the Board and was not previously required to independently challenge the obviousness determination of the dependent claims. The Court explained that "[a]rguments . . . cannot be deemed waived if they were not previously required to have been made." *Id.* at 13 (quoting *Hyatt v. Dudas*, 551 F.3d 1307, 1314 (Fed. Cir. 2008)).

The Court then turned to the merits of the Board's obviousness determination. After considering the parties' arguments whether it would have been obvious to combine ruthenium binders with PVD coatings, the Court determined that "because a person of skill in the art reading Grab would readily envisage the combination of ruthenium binders and PVD coatings, it would have been obvious to that person that these two could be combined with a reasonable expectation of success." *Id.* at 15. Based on this finding, the Court held that substantial evidence supported the Board's obviousness finding.

The Court then considered and rejected Kennametal's arguments related to secondary considerations of unexpected results. According to the Court, "the offered secondary consideration actually results from something other than what is both claimed and *novel* in the claim, [so] there is no nexus to the merits of the claimed invention." *Id.* at 16 (alteration in original) (quoting *In re Huai-Hung Kao*, 639 F.3d 1057, 1068 (Fed. Cir. 2011)).

The Court declined to consider Kennametal's arguments for patentability raised in the reply brief because "[a]rguments not raised until [the] reply brief are waived." *Id.* (second alteration in original) (quoting *Lifestyle Enter., Inc. v. United States*, 751 F.3d 1371, 1377 (Fed. Cir. 2014)).

Accordingly, the Court affirmed the Board's determinations of anticipation and obviousness.

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PTO Revival Rulings Are Not Subject to Third-Party Collateral Challenge

Mark F. Mashack

Judges: Newman (concurring), Dyk (concurring) (per curiam)
[Appealed from E.D. Va., Judge O'Grady]

In *Exela Pharma Sciences, LLC v. Lee*, No. 13-1206 (Fed. Cir. Mar. 26, 2015), the Federal Circuit affirmed a dismissal of a challenge under the APA on the ground that PTO revivals are not subject to third-party collateral challenge, thereby precluding review regardless of whether the claims were time-barred.

Patentee SCR Pharmatop ("SCR") filed its initial patent application in France and, in conformity with the PCT, filed an international patent application identifying as a designated state the United States, among others. SCR did not timely file the required materials for the U.S. application within the thirty-month statutory deadline, and, consequently, the PTO deemed the application abandoned. SCR filed a petition to revive the application, stating that the delay was "unintentional." Slip op. at 4. The PTO granted the petition, and U.S. Patent No. 6,992,218 ("the '218 patent") issued.

SCR and its exclusive licensee sued Exela Pharma Sciences, LLC, Exela Pharmsci, Inc., and Exela Holdings, Inc. (collectively "Exela"). Exela subsequently petitioned the PTO for infringement of the '218 patent under the Hatch-Waxman Act. Exela then filed the subject petition in the PTO, under the APA and 37 C.F.R. §§ 1.181, 1.182, and 1.183, challenging the PTO's revival of the patent application. The PTO declined to consider Exela's petition, finding that no statute or regulation authorizes a third-party challenge to the PTO's revival of a patent application. Following the PTO's rejection of its petition, Exela filed the present action in the district court under the APA, requesting that the district court compel the PTO to vacate the revival decision. In response, the PTO moved to dismiss the action under Fed. R. Civ. P. 12(b)(1) and (6) on several grounds, including that Exela lacked standing to challenge the PTO's revival ruling, that Exela's APA action was time-barred, and that a PTO revival is not subject to judicial review at the request of a third-party challenger. The district court dismissed Exela's action because its facial challenge to 37 C.F.R. § 1.137 was time-barred by the six-year statute of limitations.

"The Patent Act's 'intricate scheme for administrative and judicial review of PTO patentability determinations,' and 'the Patent Act's careful framework for judicial review at the behest of particular persons through particular procedures' demonstrate that third party challenge of PTO revival rulings under the APA is not legislatively intended." Slip op. at 8 (quoting *Pregis Corp. v. Kappos*, 700 F.3d 1348, 1357 (Fed. Cir. 2012)).

On appeal, the Federal Circuit first phrased the issue before it as "whether a third party may collaterally

challenge and obtain judicial review of a PTO revival ruling concerning an unrelated patent application." Slip op. at 8. The Court held that "[t]he Patent Act's 'intricate scheme for administrative and judicial review of PTO patentability determinations,' and 'the Patent Act's careful framework for judicial review at the behest of particular persons through particular procedures' demonstrate that third party challenge of PTO revival rulings under the APA is not legislatively intended." *Id*. (quoting *Pregis Corp. v. Kappos*, 700 F.3d 1348, 1357 (Fed. Cir. 2012)).

Judge Newman wrote separately to address the concern raised in Judge Dyk's concurring opinion, criticizing the Court's ruling in *Aristocrat Technologies Australia Pty Ltd. v. International Game Technology*, 543 F.3d 657 (Fed. Cir. 2008). Judge Newman explained that in *Aristocrat*, the Federal Circuit held that "the PTO's revival of an application 'is neither a fact or act made a defense by title 35 nor a ground specified in part II of title 35 as a condition for patentability.'" Newman Concurrence at 2 (quoting *Aristocrat*, 543 F.3d at 663). Judge Newman opined that "[t]he Patent Act is explicit as to the grounds for challenges to issued patents; these grounds do not include challenge to PTO discretionary actions in revival of deemed-abandoned applications." *Id.* Judge Newman further stated that "Judge Dyk correctly points out that there are areas in which 'a non-listed defense has been recognized by courts,' citing cases in which antitrust violation, patent misuse, and shop right have been recognized as defenses to patent infringement." *Id.* at 3-4 (quoting Dyk Concurrence at 4). Taking issue with Judge Dyk's statement that "such major substantive issues . . . 'cannot be so easily distinguished,'" Judge Newman stated, "If judges cannot easily distinguish the significance of antitrust violation from a missed date, we must try harder." *Id.* at 4 (quoting Dyk Concurrence at 5).

Judge Dyk wrote separately to explain why the Court's decision in *Aristocrat* was "problematic." Dyk Concurrence at 2. Judge Dyk stated that four aspects of the *Aristocrat* opinion warrant its reconsideration. First, Judge Dyk explained that *Aristocrat* did not discuss the presumption of judicial review of agency action. Second, Judge Dyk stated that the present case did not involve minor procedural error in the PTO's process. Third, Judge Dyk explained that in *Morganroth v. Quigg*, 885 F.2d 843, 846 (Fed. Cir. 1989), the Court held that review of the PTO's refusal to revive a patent application was available under the APA, but *Aristocrat* does not cite to *Morganroth*. Finally, Judge Dyk stated that *Aristocrat* failed to recognize that *Quantum Corp. v. Rodime, PLC*, 65 F.3d 1577, 1584 (Fed. Cir. 1995)—holding that a patentee who improperly enlarged the scope of its claims during reexamination, violating 35 U.S.C. § 305, was subject to a defense of invalidity—"was hardly the only example of situations in which a non-listed defense has been recognized by courts. . . . These other cases cannot be so easily distinguished from the situation in *Aristocrat* itself." Dyk Concurrence at 4-5.

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A Sufficient Controversy Exists When a Second ANDA Filer Seeks DJ of Noninfringement of an Orange-Book-Listed Patent Owned but Disclaimed by Brand Name Manufacturer

Yieyie Yang

Judges: Taranto (author), Mayer, Clevenger

[Appealed from N.D. Ill., Judge Coleman]

In *Apotex Inc. v. Daiichi Sankyo, Inc.*, Nos. 14-1282, -1291 (Fed. Cir. Mar. 31, 2015), the Federal Circuit reversed the district court's dismissal of Apotex, Inc.'s ("Apotex") complaint for DJ that Apotex will not infringe an Orange-Book-listed patent owned but disclaimed by Daiichi Sankyo, Inc. and Daiichi Sankyo Co., Ltd. (collectively "Daiichi") if Apotex manufactures or sells a generic drug bioequivalent of Daiichi's Benicar®. The Federal Circuit also reversed the district court's denial of Mylan Pharmaceuticals, Inc.'s ("Mylan") motion to intervene.

Daiichi listed two patents in the Orange Book to cover Benicar®. The first, U.S. Patent No. 5,616,599 ("the '599 patent"), covers the active ingredient of the drug, olmesartan medoxomil, and expires on April 25, 2016. Daiichi's second listed patent, U.S. Patent No. 6,878,703 ("the '703 patent"), covers methods of treatment and expires on November 19, 2021.

Mylan filed an ANDA in April 2006, certifying that both patents were invalid or would not be infringed by Mylan's proposed drug. Thereafter, Daiichi disclaimed all claims of the '703 patent and asked the FDA to remove the '703 patent from the Orange Book. The FDA did not remove the '703 patent from the Orange Book. Daiichi sued Mylan for infringing the '599 patent. The district court in that case upheld the validity of the '599 patent and entered judgment of infringement against Mylan. As such, Mylan's earliest date of market entry is October 25, 2016, six months after the expiration date of the '599 patent.

After the litigation was over, Apotex filed its own ANDA and two certifications under 21 U.S.C. § 355(j)(2)(A)(vii): (1) a Paragraph III certification accepting the result of the prior Mylan litigation with respect to the '599 patent; and (2) a Paragraph IV certification stating that Apotex's product would not infringe the '703 patent. Daiichi did not sue Apotex for infringing the '703 patent. Apotex brought a DJ action, seeking a declaration that its product would not infringe the disclaimed, but still listed, '703 patent. Mylan moved to intervene, and both it and Daiichi moved to dismiss Apotex's complaint. The district court granted Daiichi's motion to dismiss and denied Mylan's motion to intervene as moot. Apotex appealed, and Mylan cross-appealed the denial of its motion to intervene.

On appeal, the Federal Circuit first confirmed Mylan's right to intervene. To the Court, Apotex seeks to cause a forfeiture of Mylan's presumed market-exclusivity period, and Mylan has a strong, concrete monetary interest in retaining such exclusivity—180 days of more sales and/or higher prices than are likely when Apotex enters the market. The Court explained that, although Daiichi likely benefits from the exclusivity period as well, Mylan's interest exists apart from that of Daiichi.

"The patent disclaimer eliminates one, but only one, potential legal barrier to Apotex's ability to make [sales of olmesartan medoxomil] sooner rather than later. The *listing* of the patent, with its current consequence of preventing FDA approval during Mylan's presumptive exclusivity period, is another, and the parties have adverse concrete interests in the truncation or preservation of that period." Slip op. at 10.

The Federal Circuit then reversed the district court's dismissal of Apotex's complaint for lack of a case or controversy, concluding that "the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." Slip op. at 9 (quoting *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007)). In reaching this conclusion, the Federal Circuit addressed the following four issues.

First, the Federal Circuit rejected Daiichi's contention that its statutory disclaimer of the '703 patent itself means that there is no adversity between it and Apotex over stakes of a concrete character. To the Court, the concrete stakes over which Daiichi and Apotex were fighting are the revenues to be earned through selling olmesartan medoxomil. The patent disclaimer only eliminates one of the potential legal barriers to Apotex's ability to make such sales sooner rather than later. The listing of the '703 patent, with the current consequence of preventing FDA approval during Mylan's presumptive exclusivity period, is another legal barrier, and the parties have adverse concrete interests in truncating or preserving that period. The Court also explained that all three parties were likely affected by whether Apotex can cause the forfeiture of Mylan's exclusivity period. As explained by the Court, once Apotex enters the market, Daiichi and Mylan can expect to lose sales they otherwise would have made.

Second, the Federal Circuit held that Daiichi was also wrong in asserting that the delayed entry of Apotex is not "fairly traceable" to Daiichi. *Id*. at 12. The Court explained that a first filer's eligibility for marketing exclusivity is expressly conditioned on its ability to "lawfully maintain[]" a Paragraph IV certification. *Id*. (alteration in original) (quoting 21 U.S.C. § 355(j)(5)(B)(iv)(II)(bb)). According to the Court, Daiichi's original listing of the '703 patent in the Orange Book supports Mylan's exclusivity period. Had Daiichi not listed the '703 patent in the Orange Book, the '599 patent would be the only listed patent, and Mylan would have no exclusivity period. Thus, the Court concluded that Daiichi was responsible for the current existence of Mylan's exclusivity-period rights.

Third, the Federal Circuit decided that Apotex did not have to wait until it obtains tentative FDA approval of its proposed drug to support an adjudication of the request for a noninfringement judgment. The Court explained that the congressional judgment embodied in the Hatch-Waxman Act and the Court's case law make clear that "tentative approval of an ANDA is generally not a precondition to the existence of a case or controversy concerning patents listed in the Orange Book." *Id*. at 18.

Fourth, the Federal Circuit highlighted the two requirements for forfeiture under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003—a court's final decision of noninfringement that is no longer appealable (certiorari aside) and the second (or later) filer's receipt of tentative FDA approval. The first filer forfeits its exclusivity if it has not entered the market seventy-five days after those two requirements are satisfied. The Court concluded that Apotex can trigger forfeiture by obtaining a DJ of noninfringement and tentative approval, if it does both early enough in relation to Mylan's market entry.

The Federal Circuit rejected Mylan's argument that the second filer must have tentative approval before it initiates the DJ action and stressed that no such requirement could be found in the statutory text. To the Court, tentative approval is required to trigger forfeiture, and Apotex's approval status when it brought the DJ action is immaterial. The Court also rejected Mylan's argument regarding the statutory policy underlying the exclusivity period, emphasizing that the exclusivity period encourages early entry by generics into the market by providing a reward to first filers, but only up to a point. Finally, the Court distinguished the instant case from *Teva Pharmaceuticals USA, Inc. v. Sebelius*, 595 F.3d 1303

(D.C. Cir. 2010), by pointing out that the forfeiture Apotex sought to produce would not be effected by Daiichi's unilateral action but by a court judgment.

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Looking Ahead

On April 1, 2015, in *Intellectual Ventures II LLC v. JPMorgan Chase & Co.*, No. 14-1724 (Fed. Cir. Apr. 1, 2015), the Federal Circuit held that it did not have jurisdiction to review the district court's denial of JPMorgan Chase & Co.'s motion to stay pending covered business method review ("CBMR"). The Court considered whether a CBMR "proceeding" under AIA § 18(b)(2) encompasses CBMR petitions on which the Board has not yet acted. After reviewing the statutory language and legislative history, the Court explained that "the language of the statutory scheme consistently defines 'proceeding' as beginning when the [Board] institutes review." Slip op. at 11. Based on this interpretation, the Court held that it did not have jurisdiction over an interlocutory appeal denying a decision on a motion to stay until the Board institutes a CBMR proceeding. Judge Hughes dissented, asserting that the majority's opinion relied on an "overly narrow textual analysis" and was at odds with the specific purpose of the CBMR procedure. Hughes Dissent at 2.

Read the full summary in the next edition of *Last Month at the Federal Circuit*.

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Spotlight Info

In *Exela Pharma Sciences, LLC v. Lee*, No. 13-1206 (Fed. Cir. Mar. 26, 2015), the Federal Circuit affirmed a dismissal of a challenge under the APA on the ground that PTO revivals are not subject to third-party collateral challenge, thereby precluding review regardless of whether the claims were time-barred. The Court held that "[t]he Patent Act's 'intricate scheme for administrative and judicial review of PTO patentability determinations,' and 'the Patent Act's careful framework for judicial review at the behest of particular persons through particular procedures' demonstrate that third party challenge of PTO revival rulings under the APA is not legislatively intended." Slip op. at 8 (quoting *Pregis Corp. v. Kappos*, 700 F.3d 1348, 1357 (Fed. Cir. 2012)). See this month's edition of *Last Month at the Federal Circuit* for a full summary of this decision.

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